IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE GRITSTONE BIO, INC.

Lead Case No. 24-cv-03640-CRB

ORDER GRANTING MOTIONS TO DISMISS

Plaintiffs, a purported class of investors in Gritstone Bio, Inc., sue Gritstone's CEO Andrew Allen and CFO Vassiliki Economides under the securities laws for making allegedly misleading statements regarding Gritstone's work in vaccine development and manufacturing. Allen and Economides (the sole Defendants, as Gritstone is not named as a party in this action) move to dismiss Plaintiffs' complaint on the grounds that it fails to state a claim upon which relief can be granted. For the following reasons, the Court **GRANTS** Defendants' motions.

I. BACKGROUND

A. CORAL Vaccine

Gritstone Bio is a biotechnology company focused on developing next-generation vaccines using self-amplifying mRNA. Am. Compl. (dkt. 46) ¶¶ 2, 22–23. Throughout the events giving rise to this litigation, Gritstone had no commercial-stage products, meaning that it did not generate any revenue from product sales. Id. ¶ 35. Rather, Gritstone operated mostly through nonprofit and government grants. Id. As of March 2023, Gritstone had $145.8 million in liquid assets and a deficit of over $500 million, id. ¶ 36, and in August 2023 it warned that its assets would not be sufficient to fund continued

operations for a 12-month period, id. ¶ 37. Thus, in its August 2023 statement, Gritstone expressed a need for "substantial additional funding in connection with [its] continuing operations." Id.

At issue in this case is one of Gritstone's vaccine projects, CORAL, which Gritstone initiated in 2021 in an attempt to develop a vaccine for Covid-19. Id. ¶¶ 2, 24. CORAL's Phase 1 trials, which were performed on fewer than 500 patients, led to promising results as to the safety and efficacy for humans. Id. ¶¶ 26, 28. While in Phase 1, Gritstone struggled to find component parts for its CORAL vaccine that were compliant with good manufacturing practices (or, in FDA jargon, were "cGMP"). Id. ¶¶ 44–48. Even as Gritstone was preparing to transition CORAL for a Phase 2 trial in late 2023, Gritstone still lacked certain "critical" cGMP raw materials. Id. ¶ 48.

In September 2023, though, Gritstone announced that the Biomedical Advanced Research and Development Authority, or BARDA, had awarded it a $433 million contract to evaluate the CORAL vaccine in a 10,000-participant Phase 2b trial. Id. ¶ 38. Dr. Allen announced in a press release that Gritstone would plan to begin the Phase 2b trial in the first quarter of 2024, stating that "[p]reparations for the study are underway, and execution of the study will be fully funded by BARDA." Id. ¶ 39; see also Sept. 2023 Press Release (dkt. 56-8) at 1. The press release acknowledged, however, that "substantial risks and uncertainties," including uncertainties in "the regulatory approval process," "could cause Gritstone's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied" elsewhere in the press release. Sept. 2023 Press Release at 2.

As a precursor to accessing the entirety of the BARDA funds, Gritstone had until March 31, 2024 to obtain FDA approval to proceed as an investigational new drug study. BARDA Contract (dkt. 56-7) at 31. The BARDA contract explained that "[t]he Good Manufacturing Practice Regulations (GMP) will be the standard applied for clinical manufacturing, processing, packaging, storage, and delivery of this product," id. at 38, but it did not expressly provide that the raw materials for the CORAL vaccine needed to

comply with good manufacturing practices. Gritstone submitted its proposal to proceed as an investigational new drug study in November 2023. Am. Compl. ¶ 62. The FDA then notified Gritstone in December 2023 that it would not allow the Phase 2b trial to proceed, issuing a formal clinical hold letter to that effect in January 2024. Id. In the hold letter, the FDA informed Gritstone that it would "be required to use GMP-grade materials in the manufacture of the vaccine." Id. Following these communications from the FDA, Gritstone delayed its Phase 2b trial to fall 2024 "to allow use of fully GMP-grade raw materials in the vaccine." Id. ¶ 94.

In late February 2024, Gritstone issued a press release announcing that it would be reducing its workforce by 40% in light of the delay in the Phase 2b trial. Id. ¶ 106. Gritstone's stock price then fell by over 27%, and Gritstone spent the next month attempting to resolve the FDA's clinical hold on the study. Id. ¶¶ 107–14. In early April 2024, Gritstone announced that it had begun an underwritten public offering of shares of its common stock, after which stock prices fell nearly 50%. Id. ¶ 115.

B. Procedural Background

Plaintiffs are a purported class of investors in Gritstone who allege that they bought Gritstone securities at artificially increased prices. Id. ¶¶ 16–17; 126. In June 2024 they brought this action against Defendants Allen and Economides, as well as Gritstone itself, see Compl. (dkt. 1), but they amended their complaint and removed Gritstone as a defendant, see Am. Compl. ¶ 17.

Plaintiffs allege that various statements by Defendants were materially false and misleading:

- Gritstone's statements in its March 2023 Form 10-K that it had "successfully internalized all biomanufacturing steps," that it "manufacture[s] [its] products at [its] own fully-integrated good manufacturing practice (GMP) biomanufacturing facilities," that its facilities are "all designed in compliance with cGMP," that the FDA had concluded in an initial review "that the overall manufacturing and release testing for the CORAL vaccine candidates … appeared acceptable," that

"qualified third parties [] supply some components of our product candidates," and that "[a]ll internal and third-party contract manufacturing is performed under cGMP or similar guidelines." Id. ¶¶ 65–68.

- Allen's statements in a May 2023 earnings call that "[w]e look forward to continuing our work with collaborators to demonstrate the full potential of our samRNA platform" and that "[w]e expect to share additional data from our CORAL program this fall." Id. ¶¶ 70–71.
- Gritstone's statements in its May 2023 Form 10-Q that there were no material changes to the risk statements from the March 2023 Form 10-K—including the statement that third-party manufacturing is performed under cGMP or similar guidelines—and that the company's capital requirements "depend on many factors, including the scope, progress, results, and costs of developing each of our product candidates" and "potential delays in our ongoing clinical trials." Id. ¶¶ 72–74.
- Gritstone's statements in an August 2023 press release that the CORAL program yielded "promising data" and that Gritstone's "recent publication in Nature Communications demonstrates the scientific rigor of our work to date and the ability of our samRNA platform to drive potent and durable immune responses." Id. ¶¶ 76–77.
- Gritstone's statements in its September 2023 Form 8-K describing the BARDA contract, including that "the Company will receive funding of up to an estimated $433 million to conduct a 10,000 participant randomized Phase 2b comparative study" under the contract and that, based on the contract, "the Company's cash runway will be extended into the fourth quarter of 2024." Id. ¶¶ 80–81.
- Gritstone's statements in a September 2023 press release that the BARDA contract was "valued at up to $433 million," that it would entail a "10,000 participant, randomized Phase 2b double-blinded study," that "[p]reparations for the study are underway," that "execution of the study will be fully funded by

BARDA," that the "contract suppl[ies] the necessary resources to advance the development of CORAL," and that the company "look[ed] forward to initiating the Phase 2b study [] in the first quarter of 2024." Id. ¶¶ 82–83.

- Gritstone's statements in an October 2023 press release reiterating that "[p]reparations for the BARDA-funded, 10,000 subject Phase 2b, head-to-head study are underway … and we look forward to initiating the study in the first quarter of 2024." Id. ¶¶ 84–85.
- Gritstone's statements in a November 2023 press release restating the value, format, and expected timeline of the BARDA study. Id. ¶¶ 86–87.
- Gritstone's statements in its November 2023 Form 10-Q
    - restating the value, format, and expected timeline of the BARDA study;
    - stating that a "significant portion of the funding for the continued development of our next-generation samRNA vaccine candidate … is currently expected to come from the BARDA Contract," such that "if BARDA were to decline to pursue any of the gated stages [or] eliminate, reduce, delay, or object to extension for funding available to us under the BARDA contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate";
    - stating that its "ability to receive any of the remaining $423.0 million in additional funding provided for under the BARDA Contract is dependent on BARDA electing to continue to fund additional two gated stages, which it may do or not do at its sole discretion";
    - stating that if the company were "unable to complete the base period activities [obtaining FDA approval to proceed as a investigational new drug study] during the base period due to circumstances that may be either within or outside of our control … then BARDA may decide to terminate the BARDA Contract"; and

- stating that "the continuation of the BARDA Contract primarily depends on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols." Id. ¶¶ 88–91.

- Gritstone's statements in its February 2024 Form 8-K explaining the "updated timeline for the Company's Phase 2b clinical trial" whereby the trial would be postponed to fall 2024 rather than the first quarter of 2024 because, among other things, "[t]he FDA informed the Company that … the Company would be required to use fully GMP-grade materials, as well as implement certain other minor changes," and stating that "the Company estimates its cash runway will be sufficient to fund the Company's operations into the third quarter of 2024." Id. ¶¶ 94–95.
- Gritstone's statements in a February 2024 press release that it was "making the necessary preparations to begin the Phase 2b study later this year using fully GMP-grade materials in the manufacture of our self-amplifying mRNA (samRNA) vaccine." Id. ¶¶ 96–97.

Accordingly, Plaintiffs allege that Defendants violated sections 10(b) and 20(a) of the Securities Exchange Act—as well as Rule 10b-5, which the SEC promulgated under section 10(b)). See Am. Compl. ¶¶ 135–50. Defendants move to dismiss, arguing that (1) Plaintiffs fail to allege any actionable false or misleading statements, (2) Plaintiffs fail to allege sufficient facts related to scienter, and (3) Plaintiffs fail to plead that their losses were caused by any alleged misconduct. Allen Mot. (dkt. 55); Economides Mot. (dkt. 58).

II. LEGAL STANDARD

To survive a motion to dismiss, a complaint must contain sufficient factual matter to state a claim that is facially plausible. Fed. R. Civ. P. 12(b)(6); Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). A claim is facially plausible when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. The Court "must take all of the factual

allegations in the complaint as true," but it is "not bound to accept as true a legal conclusion couched as a factual allegation." Id.

A complaint alleging fraud must also "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); Kearns v. Ford Motor Co., 567 F.3d 1120, 1125 (9th Cir. 2009). Rule 9(b) requires a plaintiff to set forth the "who, what, when, where, and how" of the alleged fraud. Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir. 2003). And securities fraud claims must further meet the heightened pleading requirements of the Private Securities Litigation Reform Act: "[T]he complaint shall specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1)(B); Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 321 (2007).

III. DISCUSSION

Plaintiffs bring two claims—one under section 10(b) of the Exchange Act and one under section 20(a). Plaintiffs' section 20(a) claim is dependent on their section 10(b) claim, see Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1035 n.15 (9th Cir. 2002), so the Court begins with Plaintiffs' section 10(b) claim.

To state a claim for securities fraud under section 10(b) of the Exchange Act, a plaintiff must adequately allege "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." ESG Cap. Partners, LP v. Stratos, 828 F.3d 1023, 1032 (9th Cir. 2016) (citations omitted). SEC Rule 10b-5, which Plaintiffs also allege that Defendants violated, "implements [section] 10(b) by declaring it unlawful: '(a) To employ any device, scheme, or artifice to defraud, (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements … not misleading, or (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.'" Tellabs, 551 U.S. at 318 (quoting

17 C.F.R. § 240.10b-5). Defendants challenge the first, second, and sixth of the elements of a section 10(b) claim.

A. Materially False or Misleading Statements

To prevail on their section 10(b) claim, Plaintiffs must show either that Defendants' statements contained material falsehoods, Dura Pharmaceuticals, Inc. v. Broudo, 544 U.S. 336, 341 (2005), or that Defendants' statements omitted material information in a manner that made the statements misleading, Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1988). Materiality depends on whether "there is a substantial likelihood that a reasonable shareholder would consider" the information to be "important." Id. at 231 (citation omitted).

As for affirmative misrepresentations, statements that are mere puffery or "vague statements of optimism" are not actionable because most investors "know how to devalue the optimism of corporate executives." Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1060 (9th Cir. 2014). Likewise, forward-looking statements that are accompanied by "meaningful cautionary statements" are not actionable under the PSLRA. 15 U.S.C. § 78u-5(c)(1)(A)(i); Intuitive Surgical, 759 F.3d at 1058. This includes "any statement regarding (1) financial projections, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions 'underlying or related to' any of these issues." No. 84 Emp.-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp., 320 F.3d 920, 936 (9th Cir. 2003). And any forward statement, whether or not it is accompanied by cautionary statements, is not actionable if the plaintiff fails to allege that it was made with "actual knowledge by that person that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(B); In re Cutera Sec. Litig., 610 F.3d 1103, 1112 (9th Cir. 2010).

As for omissions, an omission is misleading only if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic, 485 U.S. at 231–32 (citation omitted). That is because the securities laws "do not create an

affirmative duty to disclose any and all material information." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011). They "prohibit only misleading and untrue statements, not statements that are incomplete." In re Rigel Pharms., Inc. Sec. Litig., 697 F.3d 869, 880 n.8 (9th Cir. 2012). Thus, disclosure is required only if it is necessary to make statements not misleading "in the light of the circumstances under which they were made." Id. (citing 17 C.F.R. § 240.10b-5(b)).

Finally, Plaintiffs "cannot rely on hindsight; rather, [they] must explain 'why the statements were false or misleading at the time they were made.'" In re Cloudera, Inc., 121 F.4th 1180, 1187 (9th Cir. 2024) (quoting Rigel, 697 F.3d at 876); see also City of Roseville Emps.' Ret. Sys. v. Sterling Fin. Corp., 47 F. Supp. 3d 1205, 1221–22 (E.D. Wash. 2014) ("[A] plaintiff may not plead 'fraud by hindsight,' i.e. a complaint may not simply contrast a defendant's past optimism with less favorable actual results.").

Plaintiffs challenge various statements that Gritstone made from March 2023 to March 2024. These statements fall into several overarching categories: (1) statements before the BARDA contract related to Gritstone's manufacturing processes, (2) statements made regarding the BARDA contract's financial value to Gritstone, and (3) statements regarding the anticipated timeline of the Phase 2b study under the BARDA contract. The Court considers each category of statements in turn.

1. Pre-BARDA contract statements

Plaintiffs challenge statements that Gritstone and Allen made in March, May, and August 2023 related to their manufacturing processes. The bulk of these statements relate to Gritstone's assurances that its facilities (where it manufactures its finished products) comply with good manufacturing practices and that its third-party contractors manufacture products "under cGMP or similar guidelines." Am. Compl. ¶¶ 65–79.[1]

[1] Plaintiffs challenge a handful of other statements from before the BARDA contract, such as Gritstone's statements that its "recent publication in Nature Communications demonstrates the scientific rigor of" its work and that it "expect[ed] to share additional data from [the] CORAL program this fall." Am. Compl. ¶¶ 66, 70. These statements are either puffery or forward-looking and therefore are not materially misleading under the securities laws.

Defendants first argue that these statements cannot give rise to section 10(b) liability because they predate the BARDA contract and the Phase 2b study. See Allen Mot. at 11. To the extent that Plaintiffs contend that these statements are false or misleading due to some relationship with the BARDA contract and the resulting study, Defendants are correct. "[A] statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." Reese v. BP Expl. (Alaska) Inc., 643 F.3d 681, 693 (9th Cir. 2011). But the Court's understanding of Plaintiffs' theory of liability is broader than Defendants' reading; as the Court sees it, Plaintiffs allege that Defendants falsely asserted that they and their third-party contractors were in compliance with good manufacturing practices when they in fact were not. See, e.g., Am. Compl. ¶ 68 ("The statements … were materially false and misleading when made … because … Gritstone failed to disclose that … Gritstone's internal and third-party contract manufacturing was not all performed under cGMP."). In other words, the BARDA contract and the Phase 2b study are relevant to these earlier statements only in that they revealed that the statements were false when made, not that they made the statements false in retrospect. This, if true, is a proper basis for section 10(b) liability.

Defendants also contend that these statements are "untethered to any particular product candidate" and thus too general to give rise to liability. See Allen Mot. at 14–15. This too misses the point. Courts find truly general statements, such as assurances of "strong governance standards," to be too general to be materially misleading or false. See, e.g., In re Paypal Holdings, Inc. Shareholder Deriv. Litig., No. 17-cv-162-RS, 2018 WL 466527, at *4 (N.D. Cal. Jan. 18, 2018). But Gritstone's statements are more specific. They claim compliance with good manufacturing practices, a term of art that means something specific in the world of drug manufacturing. And Defendants' suggestion that statements must be tethered to a specific product to be actionable is simply incorrect; the sole case that they cite on that point does not reach that conclusion. See In re Ocular Therapeutix, Inc. Sec. Litig., No. 17-12288-GAO, 2019 WL 1950399, at *6 (D. Mass. Apr. 30, 2019) ("the plaintiffs' factual allegations do not plausibly suggest that the Company's

statements or omissions were materially false or misleading at the time they were made").

That all said, most of the challenged statements were not false or misleading when viewed in their proper context. Standing alone, statements such as "[w]e have successfully internalized all biomanufacturing steps" might appear misleading given that Gritstone relied upon third-party contractors. But other statements in Gritstone's March 2023 Form 10-K made clear that Gritstone was not, in fact, representing that it internally manufactured all the component parts of the CORAL vaccine or that its third-party contractors complied with FDA regulations. Indeed, Gritstone specifically stated that it "currently lacks the internal resources and the capability to manufacture certain elements of [its] product candidates" and thus needed to "rely on qualified third parties to supply some components of our product candidates." Am. Compl. ¶ 65. Defendants therefore cannot be said to have misled with respect to the use of third-party contractors.

Gritstone's statement that "[a]ll internal and third-party contract manufacturing is performed under cGMP or similar guidelines" is more complex. On the one hand, Plaintiffs offer no allegations that Gritstone, as opposed to its contractors, did not comply with good manufacturing practices. They have failed to adequately plead that such statements were false or misleading.

On the other hand, Plaintiffs do adequately allege that Gritstone's contractors did not comply with good manufacturing practices, contrary to Gritstone's representations. See id. ¶¶ 44–47 (account of confidential witness that Gritstone knew its component materials were not cGMP).[2] To be sure, Gritstone offered clarifying statements, including that it did not "control the manufacturing process at [its contractors] and are completely dependent on them for compliance with current regulatory requirements," that it "ha[s] limited control over the ability of [its contractors] to maintain adequate quality control, quality assurance, and qualified personnel," and thus that the materials might not conform

[2] Defendants suggest that this confidential witness account is "temporally defective" because there was no need for cGMP in the Phase 1 trial that was ongoing in March 2023. Allen Mot. at 15. This is not appropriate for resolution on the pleadings, as it is a reasonable inference that Gritstone would have been looking ahead to Phase 2 and 3 trials.

to "the strict regulatory requirements of the FDA." March 2023 Form 10-K (dkt. 56-1) at 37. But warnings "that risks 'could' occur when, in fact, those risks had already materialized" do not protect a company from liability for misleading statements. In re Facebook Inc. Sec. Litig., 87 F.4th 934, 948–49 (9th Cir. 2023). According to Plaintiffs' confidential witness, Gritstone and Allen already knew that its contractors did not comply with good manufacturing practices when it issued these risk disclosures. Am. Compl. ¶¶ 44–47. Thus, at the pleading stage, Plaintiffs have adequately alleged that Gritstone's statement as to its third-party contract manufacturing being performed under cGMP or similar guidelines was misleading.[3]

Thus, of the pre–BARDA contract statements, Plaintiffs have adequately alleged that only the following statements are misleading or false: that "all … third-party contract manufacturing is performed under cGMP or similar guidelines," as well as any associated risk disclosures that characterize this risk as hypothetical rather than actual.

2. BARDA contract statements

Plaintiffs next challenge statements that Gritstone and Allen made in September, October, and November as to the financial value of the BARDA contract. Gritstone and Allen repeatedly referenced the expected value of the contract ($433 million) and how that would benefit the Company financially. See Am. Compl. ¶¶ 80–83, 86–91. Plaintiffs allege that these references, though no doubt accurate as to the terms of the contract, were misleading because Gritstone and Allen knew that they would be unable to perform under the BARDA contract given their lack of cGMP source materials. Id.

The problem with Plaintiffs' theory is that, though they properly allege that Gritstone knew that some of its source materials were not compliant with good manufacturing practices, they fail to adequately allege that Gritstone or Defendants knew that would cause problems for the BARDA contract until the FDA issued its clinical hold

[3] Defendants do not expressly contest the materiality of this statement, though some of their arguments gesture at it. See, e.g., Allen Mot. at 17 (arguing that Gritstone did not know that the FDA would require exclusively cGMP-grade source materials until January 2024, when it issued the clinical hold letter).

letter in January 2024. Am. Compl. ¶ 62. They cite an unidentified source for the proposition that the FDA requires "compliance with the cGMP regulations" whenever "drug development reaches the stage where the drug products are produced for clinical trials in humans or animals." Am. Compl. ¶ 28.[4] But Plaintiffs do not allege that, when the statements were made, it was clear that these cGMP requirements flowed down to their contractors. Plaintiffs also point to their expert, Todd Clark, who states that "regulatory agencies view raw materials as critical inputs," making compliance with cGMP "especially important." Id. ¶ 59. This after-the-fact assessment is impermissible fraud by hindsight, though, because it does not establish that Gritstone's statements were "misleading at the time they were made." Rigel, 697 F.3d at 876.

3. Phase 2b statements

Finally, Plaintiffs challenge statements that Gritstone and Allen made in September, October, and November as to the expected timeline for beginning Phase 2b trials under the BARDA contract. These statements indicated that the trials would begin in the first quarter of 2024. See Am. Compl. ¶¶ 82–87, 89–90. Like above, Plaintiffs allege that these statements, though forward-looking, are nonetheless actionable because Gritstone was unable to move on such a fast timeline given the lack of cGMP component materials. Id. This argument fails for the same reasons, though: without specific factual allegations showing that, at the time the statements were made, the contractors' lack of compliance with good manufacturing practices would necessarily delay their Phase 2b trials, Plaintiffs' arguments on this front are also fraud by hindsight.

B. Scienter

On the matter of scienter, Plaintiffs must allege facts that would establish a "strong inference" that Defendants acted with "a mental state embracing intent to deceive,

[4] A search for this phrase on Westlaw yields one source: a guideline printed in the Food Drug Cosmetic Law Reporter in 1997. See FDA, Guideline on the Preparation of Investigational New Drug Products (Human and Animal), [1997] Food Drug Cosm. L. Rep. (CCH) 310,093, 1997 WL 35396924. The Court does not consider this source sufficient—especially without citation or explanation from Plaintiffs—to establish that Defendants' knew or should have known of the cGMP requirements for source materials.

manipulate, or defraud." Tellabs, 551 U.S. at 319, 321, 323 (citations omitted). To do so, Plaintiffs must allege that Defendants made "false or misleading statements either intentionally or with deliberate recklessness." Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 991 (9th Cir. 2009) (citation omitted). Deliberate recklessness is not "mere recklessness" but is instead "an extreme departure from the standards of ordinary care" that "presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." Schueneman v. Arena Pharms., Inc., 840 F.3d 698, 705 (9th Cir. 2016) (citation omitted).

The inference of scienter "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, 551 U.S. at 314. To that end, the Court must consider "competing inferences rationally drawn from the facts alleged" to determine whether Plaintiffs' allegations, taken individually or together, create a strong inference of scienter. Id.; In re VeriFone Holdings, Inc. Sec. Litig., 704 F.3d 694, 702–03 (9th Cir. 2012).

Plaintiffs make five allegations regarding scienter: (1) that Defendants' interactions with the FDA in early 2023 meant they should have known that their contractors' lack of compliance with good manufacturing practices would be a problem, Am. Compl. ¶ 119; (2) that BARDA funding was critical to Gritstone's financial stability, id. ¶¶ 120–21; (3) that Defendants' assurances of meeting cGMP standards reflects knowledge or recklessness, id. ¶ 122; (4) that Defendants were kept informed of cGMP failings based on confidential witness accounts, id. ¶ 123; and (5) that Gritstone's and Defendants' expertise in the area of pharmaceutical regulation means they should have known that the cGMP failings would be an issue, id. ¶ 124–25.

It is first necessary to distinguish Gritstone, which is not a named Defendant in this action, from Allen and Economides. The Court can quickly dispense of Economides, as Plaintiffs allege only that she served as Gritstone's executive vice president and CFO at all relevant times, id. ¶ 19, and that she has a master's degree in public health and senior management experience at other companies in the health sciences industry, id. ¶ 125.

Economides's job titles and background are insufficient without more specific factual allegations as to how or why she would or should have known that any of Gritstone's statements were false. See Applestein v. Medivation, Inc., 561 F. App'x 598, 601 (9th Cir. 2014). Economides's statements in a sworn declaration in Gritstone's bankruptcy proceedings, which Plaintiffs cite in their brief but not in their complaint, does not go further than establishing her role at the company and her general awareness of the company's operations. Opp. (dkt. 61) at 19–20. Because Plaintiffs have not alleged specific facts that would show Economides's knowledge of whether Gritstone's contractors complied with good manufacturing practices, they have failed to allege scienter with respect to her.[5] Moreover, Plaintiffs have repeatedly failed to allege any specific facts as to Economides that would implicate her in the alleged securities fraud—Plaintiffs' citation to her bankruptcy declaration in their brief indicates there is nothing more to be said about her—so the Court denies leave to amend Plaintiffs' claim against Economides.

As to Allen, Plaintiffs allege, relying on an account from Gritstone's director of quality assurance, that Allen was at least aware of the fact that some of Gritstone's source materials were not GMP-grade. See Am. Compl. ¶ 49. Defendants argue that the Court should not credit the witness's account because the witness did not "purport[] to have had any contact with Dr. Allen on the relevant subject matters" and instead relied on hearsay from Gritstone's COO. Allen Mot. at 22. Further, Defendants point out that the witness is not clear when exactly the COO purportedly made Allen aware of the cGMP failings with respect to the source products. Id.; Allen Reply (dkt. 62) at 11–12; Am. Compl. ¶ 49.

Defendants have the better argument. Admittedly, they overreach by contending that the witness's account is irrelevant to the Court's analysis because it is indirect, as courts have rejected blanket prohibitions on considering hearsay reports by confidential

[5] Relatedly, it is unlikely that Plaintiffs have adequately alleged that Economides can even be held liable for any of the challenged statements, as she cannot be said to have "made" them. See Janus Cap. Grp., Inc. v. First Derivative Traders, 564 U.S. 135, 141 (2011) ("For purposes of Rule 10b-5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it.").

witnesses. E.g., Okla. Police Pension & Ret. Sys. v. LifeLock, Inc., 780 F. App'x 480, 484 n.5 (9th Cir. 2019) (crediting a confidential witness's report of hearsay statements made by another employee to a defendant). But an indirect confidential witness must have personal knowledge to verify the reported hearsay statements—for instance, by observing meetings between the hearsay declarant and the defendant, id.; by participating in developing reports that went to the defendants, Robb v. Fitbit Inc., No. 16-cv-151-SI, 2017 WL 219673, at *5 (N.D. Cal. Jan. 19, 2017); or by identifying specific interactions with "time, context, and details," Lloyd v. CVB Fin. Corp., 811 F.3d 1200, 1208 (9th Cir. 2016). Plaintiffs' account from the director of quality assurance, though detailed in its explanation of that witness's knowledge of the cGMP issues, lacks the detail necessary to establish that Allen knew or should have known about those issues at the time that Gritstone made the misleading statements as to cGMP.

Plaintiffs' remaining theories for proving scienter fare no better. For the reasons explained above with respect to Economides, Plaintiffs' allegations about Allen's role at the company do not establish scienter, nor do their allegations about Allen's general experience in the field. Nor does the mere fact that Allen certified Gritstone's SEC filings establish scienter, because "Sarbanes-Oxley certifications are not sufficient, without more, to raise a strong inference of scienter." Glazer Cap. Mgmt., LP v. Magistri, 549 F.3d 736, 747 (9th Cir. 2008). Finally, Gritstone's interactions with the FDA before March 2023 do not establish scienter with respect to Allen specifically—or even with respect to Gritstone as a whole. The FDA's request for "detail on the … grade of materials" along with other information, Am. Compl. ¶ 119, does not create a strong inference of scienter, as not every request for additional information necessarily implies a critical deficiency (or any deficiency at all).

Even considered together, Plaintiffs' vague and indirect witness account, the FDA's request for detail on the grade of materials, and Allen's job responsibilities and experience in the field do not tell a cohesive story of a corporate executive attempting to hide key failings from his investors. Plaintiffs' theory that Allen knowingly or with deliberate

recklessness misled investors as to the manufacturing practices of Gritstone's third-party contractors is not more likely (the standard under Tellabs, 551 U.S. at 314) than the alternative explanation that Allen, as Gritstone's CEO, was focused on bigger-picture aspects of the CORAL trials—especially since, as explained above, there was no reason for Allen or anyone at Gritstone to know that the cGMP status of source products used in the CORAL vaccine would be a dealbreaker.[6]

Thus, Plaintiffs fail to allege scienter with respect to Allen.[7]

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' motions to dismiss—without prejudice as to Allen and with prejudice as to Economides. Plaintiffs have 28 days from the issuance of this order to file an amended complaint.

IT IS SO ORDERED.

Dated: July 24, 2025

CHARLES R. BREYER
United States District Judge

[6] Plaintiffs' allegations as to misstatements in Defendants' statements related to the BARDA contract value and timeline would also fail for lack of scienter for exactly this reason. Plaintiffs have not alleged any facts that would give rise to a strong inference that Allen (or Economides) knew or was deliberately reckless as to the FDA's yet-to-be-explained requirement that they use cGMP source products in their CORAL vaccine. So even if Defendants' statements on these issues were false when made, the complaint does not support a finding that Defendants acted with scienter as to these statements.

[7] Because Plaintiffs' allegations fail either to establish (1) material misrepresentation or falsity or (2) scienter with respect to each challenged statement, the Court need not consider Defendants' loss causation argument. And because Plaintiffs' section 10(b) claim fails, so does their section 20(a) claim. See Lipton, 284 F.3d at 1035 n.15.